

### REMARKS

The present document is submitted in reply to the final Office Action dated December 29, 2008 ("Office Action").

Initially, Applicants would like to thank the Examiner for granting a telephone interview scheduled for February 9, 2009. A summary of the interview has been provided below. See "Interview Summary."

Applicants have amended claim 16 to promote clarity. Support for the amendments can be found in the specification, e.g., at page 20, lines 12-18, page 22, lines 26-28, and in FIG. 4. Applicants have also amended claim 17 to correct a typographical error and claim 22 to correct improper dependency. No new matter has been introduced.

Claims 16-20 and 22-25 are pending and under examination. Applicants respectfully request that the Examiner reconsider this application in view of the following remarks.

#### Interview Summary

During the telephone interview on February 9, 2009, Applicants' counsel pointed out that independent claim 16 covers an immunoassay kit possessing the following two structural features: (i) it contains two separable strips, and (ii) the first strip contains a test patch on which only one antibody is attached. Applicants' counsel further pointed out that these two features, set forth in the second wherein clause (a functional limitation) recited in claim 16, distinguish the claimed kit from Clemmons, US Patent No. 5,030,555 ("Clemmons"), the primary reference relied upon by the Examiner. The Examiner agreed that the above-noted two structural features render the claimed kit different from the disclosures in Clemmons but requested that Applicants amend claim 16 to directly recite them, instead of defining them in a functional limitation.

Rejection under 35 U.S.C. § 102

Claims 16, 17, and 19 are rejected for anticipation by Clemmons.

For the sole purpose of advancing prosecution, Applicants have amended independent claim 16 in the manner suggested by the Examiner, i.e., explicitly reciting in claim 16 the two structural features mentioned in the Interview Summary above. As acknowledged by the Examiner, claim 16 thus amended is novel over Clemmons. Applicants elaborate below.

Amended claim 16 covers an immunoassay kit containing two strips. As pointed out above, this kit contains two structural features: (1) the first strip includes test patches each containing **only one antibody** specific to an analyte and (2) the second strip is **separable from the first strip**.

According to the Examiner, Clemmons discloses a “dip-stick” device that anticipates the kit of claim 16. See the Office Action, pages 2-3, bridging paragraph. As shown in FIGs. 10 and 11 of Clemmons, the “dip-stick” device contains a series of test pads “102A-D.” Clemmons teaches that each test pad contains **two antibodies**, i.e., an unlabeled antibody “110” and a reporter-labeled antibody “112.” See Clemmons, FIG. 12. Differently, amended claim 16 requires that the test patch recited therein contains **only one antibody**.

Further, the test pad in the Clemmons “dip-stick” device includes a permeable membrane “106” and a matrix “108.” The Examiner states that the membrane “106” and the matrix “108” correspond to the first and second strips included in the claimed kit. See the Office Action, page 2, lines 18-22. According to Clemmons, the membrane “106” is **secured** to a backing strip “104” around the periphery thereof with the matrix “108” positioned **between** the membrane “106” and the backing strip “104.” See Clemmons, column 8, lines 53-55 and 58-62. Clearly, the membrane “106,” backing strip “104,” and matrix “108” form an intact entity. In other words, the membrane “106” and the matrix “108” are **NOT separable**. As pointed out above, the first and second strips of the kit of claim 16, which correspond to the membrane “106” and matrix “108” disclosed in Clemmons, are **separable**.

In sum, the above-discussed two structural features recited in amended claim 16 distinguish the claimed kit from the “dip stick” device of Clemmons. Applicants therefore submit that amended claim 16 is not anticipated by Clemmons. Nor are claims 17 and 19, both of which depend from claim 16.

#### Rejections under 35 U.S.C. § 103

The Examiner rejects claims 16-20, 22-23, and 24-25 for obviousness on three grounds. See the Office Action, pages 2-4, items 4, 6, and 7. Applicants address below these three grounds separately.

#### I

Claims 16, 17, and 19 are rejected as obvious over Clemmons. See the Office Action, page 2, item 4.

As discussed above, the kit of amended claim 16 includes a test patch containing **only one antibody**. As also pointed out above, the test pads of the Clemmons “dip stick” device each contain **two antibodies**, one labeled and the other unlabeled. According to Clemmons, these two antibodies form a sandwich structure with an analyte to be detected and a signal released from the labeled antibody indicates presence of the analyte. See column 9, lines 21-34; and FIGs. 13-15. Clearly, the Clemmons “dip-stick” device requires both antibodies to detect an analyte; excluding either antibody would render the device unsatisfactory for its intended purpose.

As set forth in MPEP § 2143.01, “If [a] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” See, *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Pursuant to this guideline, Applicants submit that there is no suggestion or motivation to exclude one of the two antibodies included in the Clemmons “dip-stick” device, thereby arriving at the claimed kit, as doing so would render the device useless.

For the reasons set forth above, Clemmons does not render obvious amended claim 16 and its dependent claims 17 and 19.

## II

Claims 20, 22-23, and 25, which depend from claim 16, are rejected as obvious over Clemmons in view of Reinke *et al.*, *Prostaglandins*, 37:577-86, 1989 (“Reinke”). See the Office Action, page 3, item 6.

As pointed out above, a skilled person would not have been motivated to modify the “dip stick” device disclosed in Clemmons by omitting one of the two antibodies contained therein so as to reach the kit of amended claim 16. According to the Examiner, Reinke discloses the importance of detecting thromboxane B2, a limitation of the rejected claims. See the Office Action, page 4, line 1. Clearly, this reference does not provide any motivation to modify Clemmons in the manner noted above. In other words, it does not remedy the deficiency of Clemmons.

For the foregoing reasons, Applicants submit that amended claim 16 is not obvious over Clemmons in view of Reinke. Nor are claims 20, 22-23, and 25, which depend from claim 16.

## III

Claims 18 and 24, which depend from claim 16, are rejected for obviousness over Clemmons in view of Reinke and Guire, US Patent No. 4,826,759 (“Guire”). See the Office Action, page 4, item 7.

As pointed out above, neither Clemmons nor Reinke would have prompted a skilled person in the art to modify the “dip-stick” device disclosed in Clemmons by excluding one of the two antibodies contained therein so as to arrive at the kit of claim 16. The Examiner correctly pointed out that Guire discloses leuco dyes, a limitation of the rejected claims. See the Office Action, page 4, lines 16-20. This teaching in Guire clearly does not cure the deficiency of both Clemmons and Reinke. Applicants therefore submit that the three cited references, either alone or in combination, do not render amended claim 16 obvious. Nor do they render obvious claims 18 and 24, both of which depend from claim 16.

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### CONCLUSION

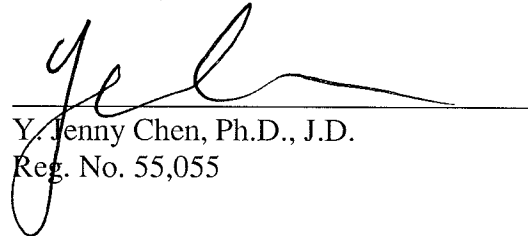
In view of the above remarks, Applicants submit that this application is now in condition for allowance. A favorable consideration is therefore respectfully solicited.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Request for continued examination fee in the amount of \$405 is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges or credits to Deposit Account No. 50-4189, referencing Attorney Docket No. 77101-002002.

Respectfully submitted,

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